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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HORNING, MICHELLE S	

ART UNIT	PAPER NUMBER
1648	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/679,710	KRIEG ET AL.	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45,46 and 94-100* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45, 46 and 94-100* is/are rejected.

7)☒ Claim(s) *97* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to communication filed 8/14/2009. The status of the claims is as follows: claims 45, 46 and 94-100 are under current examination.

To allow entry of the new rejection(s) set forth herein, the instant office action is non-final.

Claim Objections

Claim 97 is objected to because of the following informalities: missing comma between "lipid" and "a" (line 2). Appropriate correction is required.

Double Patenting-MAINTAINED

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45-47 and 94-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42, 44-53, 59, 64-69, 71-73 and 75-80 of copending Application PGPUB No. 20040087538. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method steps for stimulating an immune response, including administering a composition comprising a CG motif and an antigen for the treatment of cancer.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 45-47 and 94-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 47-52 of copending Application PGPUB No. 20050182017. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are directed to the same method steps for stimulating an immune response, including administering a composition comprising a TCG motif along with chemotherapy.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 45-47 and 94-100 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 42 and 44-48 of copending Application PGPUB No. 20070065467. Although the conflicting claims are not identical, they are not patentably distinct from each other

because both sets of claims are directed to the same method steps for stimulating an immune response, including administering a composition comprising a TCG motif to a body cavity containing a tumor.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Double Patenting-NEW

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 45, 46 and 94-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 6, 7, 12, 16 and 17 of U.S. Patent No. 7488490 in view of Dattagupta (US Patent No. 4824775), Legendre and Szoka (Pharmaceutical Research, 1992) and Lagranderie et al. (Vaccine-abstract only, 1993). Although the conflicting claims are not identical,

they are not patentably distinct from each other because both sets of claims are methods comprising the same steps including administration of unmethylated CpG-containing sequences. Note that both sets claim structures of the same length as well as non-palindromic sequences. Additionally, they are both drawn to further administering antigens, including those derived from a virus, bacterium, fungus and a tumor.

This patent does not teach a targeting means covalently bonded to the sequence (all instant claims), targeting cells including B-cells (claim 95), use of liposomes (claim 97) and administration of the sequence either orally or via injection (claims 99 and 100).

Dattagupta teaches the attachment of a specific protein or IgG for a specific cell type including B-lymphocytes receptors to a DNA via a covalent reaction (see whole document, Figure 1 and Brief Summary). Legendre and Szoka disclose a method of DNA delivery to cells using liposomes in order to mediate transfection in cells (see Abstract and whole document). Lagranderie et al. describe both oral and intradermal administration of recombinant BCG in order to induce an immune response (see Abstract and claims 46 and 99 of this reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings above and perform the method as claimed. One would have been motivated to do so in order to mediate the binding of a nucleotide sequence to a specific receptor of a cell type via an associated specific ligand or IgG (Dattagupta), successfully deliver DNA to cells by using liposomes (Legendre and Szoka) and administer DNA via known methods, including via injection

or orally (Lagranderie et al.). There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used as shown by the prior art.

Claims 45 and 94-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2 and 4 of U.S. Patent No. 7402572 in view of Dattagupta (US Patent No. 4824775), Legendre and Szoka (Pharmaceutical Research, 1992) and Lagranderie et al. (Vaccine-abstract only, 1993). Although the conflicting claims are not identical, they are not patentably distinct from each other because both claims are drawn to a method of administering sequences containing unmethylated CpG dinucleotides of the same length. Note that claim 4 is drawn to a specific non-palindromic sequence comprising GTCpGTT and this species anticipates a genius claimed by the instant application.

This patent does not teach a targeting means covalently bonded to the sequence (all instant claims), targeting cells including B-cells (claim 95), use of liposomes (claim 97) and administration of the sequence either orally or via injection (claims 99 and 100).

Dattagupta teaches the attachment of a specific protein or IgG for B-lymphocytes receptors to a DNA via a covalent reaction (see whole document, Figure 1 and Brief Summary). Legendre and Szoka disclose a method of DNA delivery to cells using liposomes in order to mediate transfection in cells (see Abstract and whole document). Lagranderie et al. describe both oral and intradermal administration of recombinant BCG in order to induce an immune response (see Abstract and claims 46 and 99 of this reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings above and perform the method as claimed. One would have been motivated to do so in order to mediate the binding of a nucleotide sequence to a specific receptor of a cell type via an associated specific ligand or IgG (Dattagupta), successfully deliver DNA to cells by using liposomes (Legendre and Szoka) and administer DNA via known methods, including via injection or orally (Lagranderie et al.). There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used as shown by the prior art.

Claims 45, 46 and 94-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-57 of U.S. Patent No. 6653292 in view of Dattagupta (US Patent No. 4824775), Legendre and Szoka (Pharmaceutical Research, 1992) and Lagranderie et al. (Vaccine-abstract only, 1993). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to a method comprising the same steps, including administering unmethylated CpG sequences of the same length (more than 8 nucleotides) which are non-palindromic for cancer therapy. Note that the same results would be expected to occur by performing the same steps. Further, note that the claimed structures of the ‘292 patent are drawn to a number of species and the species anticipate the genus of the instant application.

This patent does not teach a targeting means covalently bonded to the sequence (all instant claims), targeting cells including B-cells (claim 95), use of liposomes (claim 97) and administration of the sequence either orally or via injection (claims 99 and 100).

Dattagupta teaches the attachment of a specific protein or IgG for B-lymphocytes receptors to a DNA via a covalent reaction (see whole document, Figure 1 and Brief Summary). Legendre and Szoka disclose a method of DNA delivery to cells using liposomes in order to mediate transfection in cells (see Abstract and whole document). Lagranderie et al. describe both oral and intradermal administration of recombinant BCG in order to induce an immune response (see Abstract and claims 46 and 99 of this reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings above and perform the method as claimed. One would have been motivated to do so in order to mediate the binding of a nucleotide sequence to a specific receptor of a cell type via an associated specific ligand or IgG (Dattagupta), successfully deliver DNA to cells by using liposomes (Legendre and Szoka) and administer DNA via known methods, including via injection or orally (Lagranderie et al.). There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used as shown by the prior art.

Claims 45, 46 and 94-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 7223741 in view of Dattagupta (US Patent No. 4824775), Legendre

and Szoka (Pharmaceutical Research, 1992) and Lagranderie et al. (Vaccine-abstract only, 1993). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '741 claims are drawn to non-palindromic CpG-containing compositions combined with antigens claimed in the instant application. Because the intended use of the product claimed in the '741 patent is to administer such immunostimulatory nucleic acids, this patent anticipates the methods of administration of the instant application.

This patent does not teach a targeting means covalently bonded to the sequence (all instant claims), targeting cells including B-cells (claim 95), use of liposomes (claim 97) and administration of the sequence either orally or via injection (claims 99 and 100).

Dattagupta teaches the attachment of a specific protein or IgG for B-lymphocytes receptors to a DNA via a covalent reaction (see whole document, Figure 1 and Brief Summary). Legendre and Szoka disclose a method of DNA delivery to cells using liposomes in order to mediate transfection in cells (see Abstract and whole document). Lagranderie et al. describe both oral and intradermal administration of recombinant BCG in order to induce an immune response (see Abstract and claims 46 and 99 of this reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings above and perform the method as claimed. One would have been motivated to do so in order to mediate the binding of a nucleotide sequence to a specific receptor of a cell type via an associated specific ligand or IgG (Dattagupta), successfully deliver DNA to cells by using liposomes

(Legendre and Szoka) and administer DNA via known methods, including via injection or orally (Lagranderie et al.). There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used as shown by the prior art.

Claims 45, 46 and 94-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13 and 17-21 of U.S. Patent No. 6429199 in view of Dattagupta (US Patent No. 4824775), Legendre and Szoka (Pharmaceutical Research, 1992) and Lagranderie et al. (Vaccine-abstract only, 1993). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising the same step of administering an unmethylated CpG sequence and an antigen for cancer immunotherapy.

This patent does not teach a targeting means covalently bonded to the sequence (all instant claims), targeting cells including B-cells (claim 95), use of liposomes (claim 97) and administration of the sequence either orally or via injection (claims 99 and 100).

Dattagupta teaches the attachment of a specific protein or IgG for B-lymphocytes receptors to a DNA via a covalent reaction (see whole document, Figure 1 and Brief Summary). Legendre and Szoka disclose a method of DNA delivery to cells using liposomes in order to mediate transfection in cells (see Abstract and whole document). Lagranderie et al. describe both oral and intradermal administration of recombinant BCG in order to induce an immune response (see Abstract and claims 46 and 99 of this reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings above and perform the method as claimed. One would have been motivated to do so in order to mediate the binding of a nucleotide sequence to a specific receptor of a cell type via an associated specific ligand or IgG (Dattagupta), successfully deliver DNA to cells by using liposomes (Legendre and Szoka) and administer DNA via known methods, including via injection or orally (Lagranderie et al.). There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used as shown by the prior art.

Claims 45, 46 and 94-100 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-39 of U.S. Patent No. 6207646 in view of Dattagupta (US Patent No. 4824775), Legendre and Szoka (Pharmaceutical Research, 1992) and Lagranderie et al. (Vaccine-abstract only, 1993). Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims are drawn to methods comprising the same steps including administration of a non-palidromic CpG-containing sequence in combination with an antigen including tumor antigens. Given the same steps would lead to the same results, the instant claims are anticipated. Note that the composition claims which include species of '646 are intended to be used for administration to a subject.

This patent does not teach a targeting means covalently bonded to the sequence (all instant claims), targeting cells including B-cells (claim 95), use of liposomes (claim 97) and administration of the sequence either orally or via injection (claims 99 and 100).

Dattagupta teaches the attachment of a specific protein or IgG for B-lymphocytes receptors to a DNA via a covalent reaction (see whole document, Figure 1 and Brief Summary). Legendre and Szoka disclose a method of DNA delivery to cells using liposomes in order to mediate transfection in cells (see Abstract and whole document). Lagranderie et al. describe both oral and intradermal administration of recombinant BCG in order to induce an immune response (see Abstract and claims 46 and 99 of this reference).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings above and perform the method as claimed. One would have been motivated to do so in order to mediate the binding of a nucleotide sequence to a specific receptor of a cell type via an associated specific ligand or IgG (Dattagupta), successfully deliver DNA to cells by using liposomes (Legendre and Szoka) and administer DNA via known methods, including via injection or orally (Lagranderie et al.). There would have been a reasonable expectation of success given the underlying techniques are widely known and commonly used as shown by the prior art.

Conclusion

No claim is allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is (571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. H./
Examiner, Art Unit 1648

/Zachariah Lucas/
Primary Examiner, Art Unit 1648